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| EXAMINER | |
|---|---|
| TATE, CHRISTOPHER ROBIN | |
| ART UNIT | PAPER NUMBER |
| 1655 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 04/12/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/533,073 | LEKO, VLADIMIR | |
| | Examiner | Art Unit | |
| | Christopher R. Tate | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0405*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-24 are presented for examination on the merits.

### *Specification*

The disclosure is objected to because of the following informalities:

Throughout the specification including the title, the term "sylimarin" is misspelled. The correct spelling for this term is --silymarin--.

Appropriate correction is required.

### *Claim Objections*

Claims 1-24 are objected to because of the following informalities:

Throughout the claims, the term "sylimarin" is misspelled. The correct spelling for this term is --silymarin--.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Throughout the claims, there are numerous grammatically incorrect phrases (too numerous to individually mention), whereby transitional terms are absent - e.g., the following underlined terms are absent throughout much of the claim language a "solvent", the "solvent", the "grinding, the "defatting", the "dry extract", etc. The absence of these transitional phrase causes confusion and makes the claims unclear - including because without these transitional terms, it is unclear as to what the words following these terms are referring to (e.g., the solvent previously defined or some other solvent, the grinding step previously defined or some other grinding, the defatting step previously defined or some other defatting, the dried extract defined in a previous step or some other dried extract?). The claims should be carefully reviewed and appropriately corrected.

Claim 1 is rendered vague and indefinite for the following reasons:

- the preamble phrase "isolation of sylimarin from *Silybum Marianum* without precooling seeds" does not provide a sufficient positively-claimed limitation with respect to this apparently essential limitation within the instantly disclosed/claimed preparatory method. That is, it appears that an essential feature of the instantly claimed process is that that the *Silybum marianum* are not precooled prior to the first step of grinding. However, this limitation is not positively claimed within the body of the instantly claimed method steps. Accordingly, it is suggested that step (a) also recite this limitation by expanding step (a) to recite --grinding seeds to a fine powder, whereby the seeds have not been precooled prior to grinding-- or similar language.
- in step (b), the phrase "with hydrocarbon solvent" is grammatically incorrect. It is suggested that the term --a-- precede "hydrocarbon" within this phrase.

- in step (c), the phrase "in order to obtain sylimarin extract" is grammatically incorrect. It is suggested that the term --a-- precede "sylimarin" within this phrase.

- step (f) is awkward and unclear, as drafted - e.g., it would seem that the residue oil is separated from the dry extract but not that it the dry extract is purified within the normal sense of this scientific terminology. It is suggested the phrase --to form a dry extract-- be added at this end of step (e), and that step (f) be amended to recite --separating residue oil from the dry extract obtained in step e) to form a further defatted dry extract-- or similar language.

- step (g) is also awkward and unclear - e.g., it would seem that the final step is actually a final isolation/purification step (whereby crystals of silymarin are obtained) but this final step fails to convey this (including because it is unclear s to what is being separated, washed, and dried - e.g., the separated dried extract from step (f) or something else?). In addition, there is insufficient antecedent basis for the limitation "the obtained crystals" in step (g). It is suggested that step (g) be amended to recite --isolating crystals of silymarin from the further defatted dried extract obtained in step f)-- or similar language.

Claim 2 is grammatically awkward and confusing, as drafted. It is suggested that the phrase "that grinding is run in a mill with rotating knives and screen of up to 40 mesh" be amended to recite --that the step of grinding be done in a mill comprising rotating knives and a screen of 40 mesh or less-- or similar language.

Claim 3 is grammatically awkward and very confusing, as drafted. It is suggested that the phrase "that grinded seeds is removed into a reactor with mechanical mixer whose form is following geometry of reactor's plant". It is unclear as to what this limitation is attempting to

actually define - e.g., is this step attempting to define the grinding step (step a) of claim 1 or a post-grinding step (and if so, at what step in claim 1 is this limitation directed to)?

Claim 4 is grammatically awkward and very confusing, as drafted. In addition, there is insufficient antecedent basis for the limitation "the temperature at which solvent returns". Further, it is unclear by this latter phrase as to where the solvent is referring. With respect to the phrase "that defatting is done in an extractor", it is suggested that this phrase be expanded to recite --that the step of defatting be done in an extractor--. Also, as informality, please note that the term "claime" (line 1 of claim 4) is misspelled.

In claim 5, it is unclear as to what the phrase "that defatting is done in percolator" is defining (e.g., the defatting step of claim 1 or some other defatting). It is suggested that this phrase be amended to recite "that in step b), the defatting is done in a percolator-- or similar language.

Claim 6 recites the (plural) limitation "hexane and petrol are used as solvents for defatting" in line 2. There is insufficient antecedent basis for this limitation in the claim. Please note that claim 6 depends from claim 1 which recites a singular "solvent" being used in the step of defatting (step b).

Claim 15 recites the limitation "evaporated acetone residue" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 is unclear by the grammatically incorrect and confusing phrase "purification of dry extract from claim the 15 is done by ethers..." (lines 2-3). It is suggested that this phrase be amended to recite --the separation of the residue oil from the dry extract be done using ethers...-- or similar language. Also, based upon the suggested language set forth above for step (f) of claim

1, it is suggested that the term "purification..." in claims 17-19 be changed to --the separation of the dried extract--.

Claim 20 recites the limitation "suspension" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "crystales of purified sylimarin" in line 2. There is insufficient antecedent basis for this limitation in the claim. In addition, please note that "crystales" is misspelled.

Claims 22-24 are unclear by the recitation "characterized by the fact that product is dried in drying section". Firstly, there is insufficient antecedent basis for the term "product" in these claims (further, it is unclear as to what product this is referring to). Secondly, it is unclear as to what the drying section is referring to - i.e., dried in the drying section of what?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heidenbluth (DD 112261 - DWPI Abstract) in view of Kahol et al. (US 6,399,678).

Although difficult to interpret due to the USC 112, second paragraph rejection above, a method for isolating silymarin from *Silybum marianum* seeds via the recited steps is apparently claimed.

Heidenbluth beneficially teaches a method of isolating silymarin from *Silybum marianum* seeds (which Heidenbluth does not disclose as being pre-cooled - within the DWPI Abstract) by milling (grinding) the seeds in a high-capacity dispersing apparatus and defatting with a solvent (methylene chloride: $CH_2Cl_2$). The defatted seeds are extracted with a medium polarity solvent (acetone) and evaporated. The residue oil is removed therefrom - thus defatted again (using $CH_2Cl_2$) and dried. The crude product is further purified via extraction and separation steps so as to recrystallize the silymarin therefrom (thus, obtaining crystals of silymarin having a relatively high purity) - see DWPI English Abstract. Heidenbluth does not expressly teach using other solvents to defat the seeds, nor certain other claim limitations (as best understood - based on indefinite/unclear language used within the instant claims).

Kahol et al. beneficially teach that hydrocarbon solvents such as hexane are effective solvents for defatting ground *Silybum marianum* seeds, whereby the seeds are first ground then defatted using such a hydrocarbon solvent, within an overall method for isolating silymarin therefrom. Kahol et al. also beneficially teach other working parameters instantly claimed for effectively isolating silymarin therefrom including using a percolator or an extractor during the defatting step(s), final purification step(s) involving filtering, washing with distilled water, and drying to obtain the silymarin crystals, as well as other claimed working parameters (see entire document including cols 2-3, and working examples).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute a hydrocarbon solvent within the defatting step(s) taught by Heidenbluth (and to grind the *Silybum marianum* seeds prior to defatting) - as well as to utilize a percolator or extractor for such purpose, and to further include conventional final purification steps (such as filtering, washing, and drying) used to obtain silymarin crystals, based upon the beneficial teachings provided by Kahol et al. as discussed above. The adjustment of these and other types of conventional working conditions (e.g., determining appropriate ratios of solvents to seeds - such as hexane or acetone to seed mass - or temperature and pressure ranges; and/or using one or more other commonly-employed hydrocarbon solvents; etc.) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655